

### **REMARKS**

Reconsideration of this application, as amended, is respectfully requested. Claims 1-17 were pending, and have been cancelled without prejudice or disclaimer. The Applicant reserves the right to prosecute the subject matter of any of the cancelled claims in a continuing application. New claims 18-33 have been inserted with this response. Applicant maintains that these amendments do not add any new matter.

### **REJECTIONS UNDER 35 U.S.C. § 101**

The Examiner rejected claims 1 and 10 and their dependent claims under 35 U.S.C. § 101. The Examiner suggested insertion of "isolated" or "purified" into the claims to distinguish these products from naturally occurring products. Independent Claim 18 claims a composition comprising "two, three, or four distinct purified protein-polysaccharide conjugates"; all other claims are dependent. Therefore, Applicant respectfully requests that this rejection be withdrawn.

### **REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

The Examiner rejected claims 1-8 and 10-16 under 35 U.S.C. § 112, second paragraph, as being indefinite. Certain claims were rejected as being improperly dependent, or as containing improper antecedent basis. This rejection is rendered moot by the cancellation of these claims. Therefore, Applicant respectfully requests that this rejection be withdrawn.

### **REJECTIONS UNDER 35 U.S.C. § 102(b)**

The Examiner rejected claims 1-3, 5-7, 10, 11 and 13-15 under 35 U.S.C. § 102(b) as being anticipated by Costantino et al. Vaccine 10:691-698 (1992), Lieberman et al., JAMA, 275:1499-1503 (1996), or Twumasi et al., J. Infect. Dis. 171:632-638 (1995). Applicant respectfully disagrees with these rejections, as indicated below.

Claims 1-3, 5-7, 10, 11 and 13-15 are said to be anticipated by Costantino et al. Vaccine 10:691-698 (1992). The Examiner states that Costantino teaches an immunogenically effective amount of a meningococcal A and C conjugate vaccine (i.e.,

multivalent vaccine). Independent claim 18 is directed to an immunological composition comprising two, three, or four distinct purified protein-polysaccharide conjugates wherein at least one serogroup is W-135 or Y. The rejection does not establish that Constantino et al. teaches the instantly claimed immunological composition. As such, Applicant respectfully requests that this rejection be withdrawn.

Claims 1-3, 5-7, 10, 11 and 13-15 are said to be anticipated by Lieberman et al., JAMA, 275:1499-1503 (1996). The Examiner states that Lieberman discloses an immunogenically effective amount of a combination meningococcal conjugate vaccine (i.e., multivalent vaccine) comprising depolymerized capsular polysaccharides from groups A and C *N. meningitidis* conjugate to a protein carrier. Independent claim 18 is directed to an immunological composition comprising two, three, or four distinct purified protein-polysaccharide conjugates wherein at least one serogroup is W-135 or Y. The rejection does not establish that Lieberman et al. teaches the instantly claimed immunological composition. As such, Applicant respectfully requests that this rejection be withdrawn.

Claims 1-3, 5-7, 10, 11 and 13-15 are said to be anticipated by Twumasi et al., J. Infect. Dis. 171:632-638 (1995). The Examiner states that Twumasi teaches an immunogenically effective amount of a group A plus group C meningococcal polysaccharide conjugate vaccine. Independent claim 18 is directed to an immunological composition comprising two, three, or four distinct purified protein-polysaccharide conjugates wherein at least one serogroup is W-135 or Y. The rejection does not establish that Twumasi et al. teaches the instantly claimed immunological composition. As such, Applicant respectfully requests that this rejection be withdrawn.

Claims 1-3, 5-7, 10, 11 and 13-15 were rejected under 35 U.S.C. § 102(b) as being anticipated by Granoff (WO 98/58670). The Examiner states that Granoff discloses a bivalent meningococcal serogroup A and C oligosaccharide-protein conjugate vaccine wherein meningococcal serogroup A and C oligosaccharides are conjugated to a diphtheria protein and shows that antibody responses are elicited by the vaccine.

Independent claim 18 is directed to an immunological composition comprising two, three, or four distinct purified protein-polysaccharide conjugates wherein at least one serogroup is W-135 or Y. The rejection does not establish that Granoff teaches the instantly claimed immunological composition. As such, Applicant respectfully requests that this rejection be withdrawn.

#### **REJECTIONS UNDER 35 U.S.C. § 103(a)**

The Examiner has rejected claims 1, 6, 8, 10, 14 and 16 under 35 U.S.C. § 103(a) as being unpatentable over Granoff (WO 98/58670). Claims 1, 6, 8, 10, 14 and 16 have been cancelled. The rejection is, therefore, moot. Applicant does not believe these rejections are applicable to new claims 18-33.

The Examiner has rejected claims 1, 4, 10 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Granoff (WO 98/58670). The Examiner states that Granoff teaches immunologically effective amounts of a meningococcal capsular polysaccharide-protein conjugate and the tetravalent Menomune polysaccharide vaccine comprising serogroups A, C, Y and W-135 meningococcal capsular polysaccharides. The Examiner also states that Granoff teaches the disadvantages of the Menomune polysaccharide vaccine. The Examiner therefore concludes that it would have been *prima facie* obvious to one of ordinary skill in the art to be motivated to produce the instantly claimed invention. Applicant respectfully disagrees, as indicated below.

The Federal Circuit has repeatedly held that the art must contain some suggestion or incentive to motivate the skilled artisan to modify a reference or to combine references. For there to be a *prima facie* case of obviousness, the suggestion must come from the prior art, either literally or from the prior art as "filtered through the knowledge" of the skilled artisan, and provide a reasonable expectation of success. *Motorola v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1472, 43 U.S.P.Q.2D (BNA) 1481, 1489 (Fed. Cir. 1997). In addition, neither the suggestion nor the expectation of success may come from the Applicant's disclosure. *In re Dow Chemical Co. v. American Cyanamid Co.*, 837 F.2d 469, 5 U.S.P.Q. 2d 1529 (Fed. Cir. 1988). Applicant respectfully maintains that the Examiner has not made the *prima facie* case of obviousness.

The Examiner states in the Office Action that "[Granoff does] not expressly disclose a multivalent meningococcal conjugate vaccine wherein the serogroup A, C, W-135 and Y meningococcal polysaccharides are conjugated to one or more carrier proteins." Thus, as admitted by the Examiner, Granoff does not literally suggest the instantly claimed invention.

The Examiner also alleged that because there were art-recognized disadvantages in Menomune (polysaccharide A, C, Y, W-135), the skilled artisan would have combined that observation with Granoff's suggestion to make a conjugated polysaccharide vaccine to A and C or A, B and C, and been motivated to make an A/C/Y/W-135 conjugate vaccine. The Examiner is apparently saying that the suggestion to make a conjugate vaccine containing Y and/or W-135 is derived from Granoff and the art-known deficiencies in Menomune "filtered through the knowledge" of one of skill in the art. Applicant respectfully disagrees.

Applicant believes the Examiner must admit that: 1) Granoff qualifies as one of skill in the art; and, 2) Granoff knew of both Menomune's deficiencies and his own disclosure. Applicant believes that Granoff is exemplary of a skilled artisan who, if the Examiner is correct, would have been motivated to produce the instantly claimed invention. However, following a discussion of the deficiencies of Menomune, Granoff explicitly leaves out any reference to Y or W-135 in the description of possible conjugates, suggesting only A/C and A/C/B as possible conjugate vaccines (see Granoff at p. 12). If the Examiner is correct, Applicant believes Granoff would have explicitly suggested a conjugate containing Y and/or W-135. The fact remains, however, that Granoff did not make such a suggestion. Thus, even Granoff himself, having all of the information relied upon by the Examiner, was not motivated to suggest the instantly claimed invention. Applicant respectfully maintains that the only additional evidence the Examiner has relied upon in making this rejection is the Applicant's own disclosure and hindsight, which is clearly improper.

Furthermore, Applicant strongly believes that, even if the Examiner maintains that the skilled artisan would have been motivated to make an A, C, Y, W-135 vaccine, Granoff does not provide a reasonable expectation of success in generating or using the instantly claimed invention as a human vaccine. Granoff provides no information

whatsoever with respect to Y and W-135 conjugates. Granoff provides neither any guidance for making a Y or W-135 conjugate nor any experimental results on the use of such conjugates as human vaccines. Thus, Applicant does not believe Granoff provides the skilled artisan with a reasonable expectation of success in making or using the instantly claimed invention.

Applicant does not believe that Granoff provides either a suggestion, motivation, or reasonable expectation of success in producing instantly claimed invention. Applicant respectfully maintains that the Examiner has not made a *prima facie* case of obviousness, as alleged. As such, Applicant requests that this rejection be withdrawn.

### OBJECTIONS

Claims 1, 2 and 16 were objected to and have been cancelled. The objections raised as to these claims are, therefore, moot.


### CONCLUSIONS

Applicant respectfully requests favorable consideration of the currently pending claims in view of the foregoing remarks and believe the current claims are in condition for allowance. The Examiner is encouraged to contact the undersigned if it is believed this would expedite prosecution.

Respectfully submitted,

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